UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED, et al., **Plaintiffs,** **v.** **PADAGIS ISRAEL PHARMACEUTICALS LTD, et al.,** **Defendants.**	**Civil Action No. 2:20-cv-05426-SRC-CLW (CONSOLIDATED)** **OPINION**

I. Introduction

This matter comes before the Court on the motion of defendants/counterclaim plaintiffs Padagis Israel Pharmaceuticals Ltd and Padagis US LLC ("Padagis")[1] seeking to amend their answer to the complaint of plaintiffs/counterclaim defendants Bausch Health Ireland Limited, Bausch Health Americas Inc., and Bausch Health US, LLC ("Bausch") to assert a counterclaim of inequitable conduct [ECF No. 46]. Bausch has opposed the motion and Padagis has filed a reply. ECF No. 49, 50. The Court has carefully considered the parties' submissions and decides the matter without oral argument pursuant to Local Civil Rule 78.1. For the reasons stated below, the Court GRANTS Padagis' motion.

[1] Padagis was recently substituted for the original defendants/counterclaim plaintiffs Perrigo Israel Pharmaceuticals Ltd. and Perrigo Company plc. See ECF No. 72. Although this motion was submitted by the Perrigo entities, the Court will refer to these parties as Padagis. See id. at ¶ 5(a) ("[A]ll prior references to Perrigo Israel Pharmaceuticals Ltd. in Court pleadings or any other materials filed or served in this case will be understood to apply to Padagis Israel Pharmaceuticals Ltd and all prior references to Perrigo Company plc in Court pleadings or any other materials filed or served in this case will be understood to apply to Padagis US LLC.").

II. Background

Bausch filed this action in May 2020, alleging Padagis' infringement of U.S. Patent Nos. 8,809,307 (the "'307 Patent") and 10,478,502 (the "'502 Patent") through Padagis' filing of an Abbreviated New Drug Application ("ANDA") for Padagis' generic product Bryhali, wherein Padagis alleged that these patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Bryhali. ECF No. 1 ("Bryhali"). Bausch then filed an action asserting similar allegations concerning the '307 Patent, the '502 Patent, U.S. Patent Nos. 10,251,895 (the "'895 Patent") and 10,426,787 (the "'787 Patent"), and Padagis' ANDA for its generic product Duobrii. Civil Action No. 2:20-cv-11807-SRC-CLW, ECF No. 1 ("Duobrii"). After the cases were consolidated, with Bryhali designated as the lead case, Padagis filed answers with counterclaims in response to both complaints. ECF No. 19, 25, 28.

Padagis now seeks leave to amend its answer to the Duobrii complaint to assert an affirmative defense and counterclaim grounded in alleged inequitable conduct by the named inventors of the '895 and '787 patents (Gordon Dow, Radhakrishnan Pillai, and Varsha Bhatt (the "Inventors"))[2] and/or related entities who owed a duty of candor to the United States Patent and Trademark Office (the "PTO")[3] in connection with the prosecution of these patents. Duobrii at ¶¶ 28, 32. Padagis' proposed amended answer (the "PAA," ECF No. 46-1) asserts that these entities violated their duty of candor by misrepresenting and failing to disclose certain information which,

[2] Plaintiff Bausch Health US, LLC is the '895 and '787 patents' assignee. Duobrii at ¶¶ 30, 34.

[3] Under 37 C.F.R. § 1.56(a), "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [Patent] Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." This duty applies to each named inventor and prosecuting attorney, as well as anyone "who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

if properly presented, would have resulted in the '895 and '787 patents being declared invalid. Padagis therefore seeks a judgment that these patents are unenforceable. See PAA at Eighth Affirmative Defense; Ninth Counterclaim; Wherefore Clause, para. D.

III. Legal Standards

Under Rule 15(a), "a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires." The "three instances when a court typically may exercise its discretion to deny a Rule 15(a) motion for leave to amend [are] when '(1) the moving party has demonstrated undue delay,[4] bad faith or dilatory motives, (2) the amendment would be futile, or (3) the amendment would prejudice the other party.'" United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co., 839 F.3d 242, 249 (3d Cir. 2016) (quoting U.S. ex rel. Schumann v. Astrazeneca Pharm. L.P., 769 F.3d 837, 849 (3d Cir. 2014)). "A court denies a motion to amend on futility grounds if the complaint, as amended, would fail to state a claim upon which relief could be granted. We assess futility with the same standard of legal sufficiency as applies under Rule 12(b)(6)." Woodend v. Lenape Reg'l High Sch. Dist., 535 F. App'x 164, 168 (3d Cir. 2013) (citations and quotation marks omitted).[5] To withstand a Rule 12(b)(6) motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007) (quotation marks omitted)). In conducting this analysis, a court must "accept as true all of the

[4] Padagis brought its motion within the time for the parties to move to amend their pleadings. See ECF No. 41 at 4.

[5] "[C]ourts use the same standard in ruling on a motion to dismiss a counterclaim under Rule 12(b)(6) as they do in assessing a claim in a complaint." Idenix Pharm., Inc. v. Gilead Scis., Inc., 2014 U.S. Dist. LEXIS 118789, at *18 (D. Del. Aug. 25, 2014) (citing Tyco Fire Prods. LP v. Victaulic Co., 777 F. Supp. 2d 893, 898-99 (E.D. Pa. 2011)).

factual allegations, as well as all reasonable inferences, reasonably drawn from the complaint, and view them in the light most favorable to the [party seeking amendment]." Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997) (citing cases).

Because Padagis seeks to allege fraudulent conduct, "[t]he Rule 12(b)(6) standard of review is . . . altered by Rule 9(b), which imposes a heightened pleading requirement of factual particularity with respect to allegations of fraud." In re PDI Sec. Litig., 2006 U.S. Dist. LEXIS 80142, at *5 (D.N.J. Nov. 2, 2006). Rule 9(b) provides that "[i]n alleging fraud . . ., a party must state with particularity the circumstances constituting fraud . . . . Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Within the present context,

> the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. Moreover, although "knowledge" and "intent" may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO. . . .
>
> A reasonable inference is one that is plausible and that flows logically from the facts alleged, including any objective indications of candor and good faith.

Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1328-29 and n.5 (Fed. Cir. 2009) (citing Greenstone v. Cambex Corp., 975 F.2d 22, 26 (1st Cir. 1992), superseded by statute on other grounds, Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737.[6] Importantly, though, "[w]hile Rule 9(b) requires pleading with specificity, it does not erase the general standard that the Court should draw reasonable inferences in favor of [the party seeking

[6] "While pleading standards in patent cases generally follow that of the applicable regional circuit court, when assessing the level of particularity required by a claim of inequitable conduct under Rule 9(b), this Court applies the law of the Federal Circuit." Targus Int'l Llc v. Victorinox Swiss Army, Inc., 2021 U.S. Dist. LEXIS 105221, at *13 (D. Del. June 4, 2021) (citing Exergen, 575 F.3d at 1326).

amendment]." FTC v. Wyndham Worldwide Corp., 10 F. Supp. 3d 602, 631 (D.N.J. 2014) (quoting Flood v. Makowski, 2004 U.S. Dist. LEXIS 16957, at *42 (M.D. Pa. Aug. 24, 2004)).

IV. Analysis

a. The Sugarman Declaration

Padagis' primary argument arises from a declaration of Jeffrey Sugarman, M.D. which was submitted to the PTO in July 2018 in support of the '895 and '787 patents. ECF No. 46-5 (the "Sugarman Decl."); see also ECF No. 46-4 at 11; 46-16 at 12. Dr. Sugarman averred there that "the achievement of the clinical results of the Invention [was] unexpected and very surprising to a person of ordinary skill in the art." Sugarman Decl. at ¶ 7. More specifically, he "was very surprised when the applicants showed the results of the clinical trials of the Invention to me. . . . [T]he Invention unexpectedly achieved the synergistic efficacy over the combination of halobetasol proprionate and tazarotene monotherapies." Id. at ¶ 11. This is problematic, Padagis argues, in view of an article published by Dr. Sugarman the previous year in the Journal of Drugs in Dermatology entitled "A Phase 2, Multicenter, Double-Blind, Randomized, Vehicle Controlled Clinical Study to Assess the Safety and Efficacy of a Halobetasol/Tazarotene Fixed Combination in the Treatment of Plaque Psoriasis". ECF No. 46-7 ("Sugarman 2017"). There, Dr. Sugarman wrote that "Tazarotene has been shown to be an effective treatment for psoriasis. Use of topical tazarotene is limited by its potential irritancy. However, combining a topical corticosteroid [such as halobetasol propionate, with tazarotene] is one option that may prevent the irritancy effects of tazarotene **while providing a synergistic therapeutic effect** as well as a potential decrease in steroid-induced atrophy." Id. at 2-3 and n.10 (citing Kaidbey K, Kopper SC, Sefton J, et al. A pilot study to determine the effect of tazarotene gel 0.1 % on steroid-induced epidermal atrophy, Int'l Journal of Dermatology 40:468-471 (2001) ("Kaidbey 2001")) (emphasis added).

Hence the claimed fraudulent conduct: by stating in 2018 that he was surprised to see the same synergistic therapeutic effect that his own article demonstrates he was aware of no later than 2017 — and in fact, was in the prior art since the publication of Kaidbey 2001 — Dr. Sugarman (and by extension, the Inventors) violated the duty of candor owed to the PTO, in turn rendering the '895 and '787 patents invalid. Cf., e.g., Hycor Corp. v. Schlueter Co., 740 F.2d 1529, 1538 (Fed. Cir. 1984) ("A breach of the duty of candor owed to the PTO, that prevents the grant of a patent or causes it to be held invalid or unenforceable, occurs when material information is misrepresented or withheld, and such misrepresentation or withholding is intentional or accompanied by gross negligence or bad faith."); see also Sugarman Decl. at ¶ 13 ("I further declare that . . . willful false statements may jeopardize the validity of the application or any patents issuing therefrom.").

Although not raised by Bausch, there exists a close threshold question of whether there is, in the first instance, any clash between the Sugarman Decl. and Sugarman 2017 as alleged. The Sugarman Decl. includes the following:

> although potent corticosteroids and tazarotene have been used or attempted for the treatment of psoriasis, they had not been shown to be effective **at low concentrations** at the time of the Invention. In fact, at the time of the Invention, people of ordinary skill in the art did not believe that the combination of **a low concentration of halobetasol proprionate and a low concentration of tazarotene** would be effective for treating psoriasis. Prior to the Invention, clinical practice in topical treatment of psoriasis was to use the most potent drugs at the highest tolerable strength.

Sugarman Decl. at ¶ 10 (emphasis added). It thus is plausible to interpret the Sugarman Decl. as conveying that the prior art showed corticosteroids and tazarotene to be effective in treating psoriasis, just not at a low concentration — that was what was surprising about the Invention. Under such a construction, Padagis' proposed amendment is futile, since there is no conflict

between the statement at issue in Sugarman 2017 (i.e., corticosteroids and tazarotene may synergistically treat psoriasis) and the Sugarman Decl. (i.e., the Invention was surprising in that it made such treatment possible at low concentrations).

As it must do on this motion, however, see Wyndham Worldwide, supra, the Court will construe these statements in favor of Padagis. Simply put, the assertions in the Sugarman Decl. that Dr. Sugarman was surprised that the Invention unexpectedly achieved synergistic efficacy in treating psoriasis conflict with the notion in Sugarman 2017 that combining a corticosteroid with tazarotene provides a synergistic therapeutic effect. Moreover, Dr. Sugarman's expression of surprise at this effect is somewhat less tethered to low concentrations than as expressed elsewhere in the Sugarman Decl., i.e., in connection with the Invention's reduction in side effects.[7] Compare Sugarman Decl. at ¶ 11 ("The Invention unexpectedly achieved the synergistic efficacy over the

[7] The PAA's reference to the Invention's synergistic reduction in side effects warrants brief discussion, as the proposed amendment contains numerous references to this benefit in the context of both Sugarman 2017 and the Sugarman Decl. See PAA at, e.g., ¶¶ 59, 75 (quoting the Sugarman Decl. for the "addition[al]" notion that "although corticosteroids have been observed to reduce the severity of skin reactions when used in conjunction with tazarotene, people of ordinary skill in the art expected that such benefit required much higher corticosteroid concentration of halobetasol proprionate in the Invention. . . . Therefore, I was surprised to see that a low concentration of 0.01% halobetasol proprionate could be enough to significantly reduce the side effects of tazarotene monotherapy. . . ."); id. at ¶¶ 62, 78, (quoting Sugarman 2017's statement that "combining a topical corticosteroid [such as halobetasol propionate, with tazarotene] is one option that may prevent the irritancy effects of tazarotene"). Despite these and similar citations, while Padagis seeks to allege that "Dr. Sugarman's surprise regarding 'synergistic efficacy' in his 2018 declaration is contradicted by his own prior publication regarding the combination of halobetasol and tazarotene", id. at ¶¶ 62, 78, Padagis does not appear to make a parallel allegation in connection with Dr. Sugarman's surprise at the synergistic reduction in side effects. This appears consistent with the fact, alluded to above, that Dr. Sugarman's surprise at the Invention's reduction of side effects was specifically due to this occurring at low concentrations, Sugarman Decl. at ¶ 12, something that Sugarman 2017 does not convey.

As directly relevant to this motion, the PAA's allegations concerning Dr. Sugarman's surprise at the Invention's reduction in side effects, were they to stand alone, likely would not pass Rule 12(b)(6) muster, since they do not appear to conflict with Sugarman 2017. Likewise, Padagis' assertions as to the Inventors' failure to submit to the PTO Dr. Sugarman's curriculum vitae or publication list, or Sugarman 2017 itself, do not support a finding of misconduct. Because, however, these allegations provide a certain degree of context and color to — and may ultimately support — those that are directly actionable, the Court will permit the proposed amendment in its entirety.

combination of halobetasol proprionate and tazarotene monotherapies . . . .") with Sugarman Decl. at ¶ 12 ("I was surprised to see that a low concentration of 0.01% halobetasol proprionate could be enough to significantly reduce the side effects of tazarotene monotherapy. . . . "). To this end, in the Notice of Allowability, the patent examiner expressly noted that the prior art was "silent on the disclosed synergistic effect of halobetasol-proprionate and tazarotene at yielding . . . functional effects at any concentration, let alone at a concentration of 0.01% wt. halobetasol-proprionate and 0.045% wt. tazarotene", ECF No. 46-6 at ¶ 12, further suggesting that the Invention's synergistic efficacy (as opposed to synergistic efficacy specifically at low concentrations) was key in construing the Invention as non-obvious and therefore patentable. The Court thus finds, at bottom, sufficient indicia of misrepresentation in the Sugarman Decl. to permit Padagis to conduct discovery on this issue.

Turning to Bausch's opposition, two points are raised — each couched within Rule 9(b), and neither of which compels denial of the motion. Bausch first asserts that while the Sugarman Decl. states that the Invention was unexpected and surprising "at the time of the Invention, namely as of 2015," Sugarman 2017 was written two years later. ECF. No. 49 at 5-6. Thus, the argument goes, there is no fraud in Dr. Sugarman stating he was surprised at the Invention's effects in 2015, and thereafter, in 2017, writing that such effects were commonly known.

This argument fails on two counts. First, although the Sugarman Decl. references the prior art "at the time of the Invention," it more directly states that Dr. Sugarman was "very surprised when the applicants showed the results of the clinical trials of the Invention to [him]." Sugarman Decl. at ¶ 11. As Padagis correctly notes, there is no indication in the Sugarman Decl. (or evidence on this motion, for that matter) as to when the applicants showed the clinical trial results to Dr. Sugarman. On the present record, therefore, the Court must resolve this uncertainty in Padagis'

favor. Second, even assuming that Dr. Sugarman saw these results in 2015, Sugarman 2017's reference to Kaidbey 2001 suggests that synergistic efficacy was known in the prior art as early as 2001.

To this end, the Court likewise rejects Bausch's argument that the PAA fails to make specific reference to Kaidbey 2001. The PAA cites the statement in Sugarman 2017 which relies on Kaidbey 2001, PAA at ¶¶ 62, 78, as well as attaches Sugarman 2017, whose reference to Kaidbey 2001 is evident. Rule 8 requires "a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests". Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)). Bausch plainly is on fair notice that Padagis' counterclaim relies upon Kaidbey 2001.

Finally, the Court notes that the proposed amendment safely allows for the requisite who, what, when, where, and how inferences to be reasonably drawn, as well as for the knowledge and intent inferences as conveyed in Exergen, supra. Dr. Sugarman obviously knew in 2018 of the information conveyed in Sugarman 2017, and a realistic view of the Sugarman Decl. makes it "plausible and . . . flow[] logically" that Dr. Sugarman withheld this information with a specific intent to deceive the PTO; i.e., to avoid the consequence of conceding that the synergistic therapeutic effect was known in the prior art. The court in Allergan United States v. Prollenium Us, 2020 U.S. Dist. LEXIS 253760 (D. Del. Apr. 15, 2020) reached the same conclusion under nearly identical circumstances:

> The allegations in the SACC regarding Dr. Lebreton's own experiments and tests further support a reasonable inference that Dr. Lebreton intended to mislead the USPTO in his declaration. The SACC alleges that Dr. Lebreton's experiments were performed in 2005, and those experiments showed that lidocaine could be successfully incorporated into products containing crosslinked-HA.

> These facts give rise to a reasonable inference that Dr. Lebreton knew his declaration that such results amounted to a "surprising and unexpected discovery" three years later in August 2008 was false. Based on the allegations made in the SACC, it is reasonable to infer that Dr. Lebreton misrepresented the results of his experiments with the specific intent to deceive the USPTO.

Id. at *18-19 (citing Exergen) (citations omitted). Conversely, this case is a far cry from Warner Chilcott Co., LLC v. Amneal Pharm., LLC, 2013 U.S. Dist. LEXIS 177557 (D.N.J. Nov. 19, 2013), relied upon by Bausch, where

> Defendants have not alleged Plaintiffs thwarted the examiner in any way. Defendants recite the right words, that the Applicants "incorrectly asserted that the prior art 'taught away'" and that "the applicant misrepresented the prior art," but these phrases alone are conclusory. Defendants do not support the allegations with facts that demonstrate that misstatements were made. The examiner had the [prior art] references, and Plaintiffs listed them in the original patent application. . . . Missing are allegations that the Applicants withheld information relating to the references, submitted false information, or misrepresented material facts that would hamper the examiner's ability to accept or reject the Applicants' arguments.

Id. at *25-26 (citation omitted).

The Court therefore will grant Padagis' request to amend its answer and counterclaims to include allegations of misconduct relating to the Sugarman Declaration.

b. Study NCT02045277

Padagis also seeks to add allegations concerning Bausch's failure to disclose certain information concerning study NCT02045277, entitled "A Phase 2, Multicenter, Double-Blind, Randomized, Vehicle Controlled Clinical Study to Assess the Safety and Efficacy of a IDP-118 in the Treatment of Plaque Psoriasis" ("NCT02045277"). According to Padagis, this study, which is publicly available on ClinicalTrials.gov, lists Bausch Health Americas, Inc. as sponsor, Dow Pharmaceutical Sciences as collaborator, and Dr. Binu Alexander (who is a co-author of Sugarman 2017) as central contact. Padagis alleges upon information and belief that NCT02045277 is the

same study disclosed in the '895 and '787 patents and is the same study at issue in Sugarman 2017. PAA at ¶¶ 66-67, 82-83.

Padagis more pointedly alleges that the information for NCT02045277 posted on ClinicalTrials.gov has been amended several times since it was first published in 2014. The first several versions identified a lotion containing halobetasol propionate 0.01% and tazarotene 0.045% as being used to treat psoriasis. In August 2016, the study information was edited (upon information and belief, by one or more of the Inventors or others owing a duty of candor to the PTO) to remove the listed concentrations of halobetasol propionate and tazarotene. Padagis seeks to allege that the failure to submit information regarding the study further renders the '895 and '787 patents unenforceable. See PAA at ¶¶ 66-71; 82-87.

Bausch counters that the information at issue was disclosed in the patent specifications themselves; that the versions of the study with removed information were submitted to ClinicalTrials.gov, not to the PTO; and that the earlier versions still are available — albeit with some searching — on the ClinicalTrials.gov website. These arguments misconstrue the nature of Padagis' proposed amendment. It is not the information itself that underlies the claimed misconduct. Instead, it is the fact that this information was available in the prior art, something that the information itself (submitted to the PTO only in the context of prior clinical trials) does not reveal. Similarly, the fact that this information was submitted to, and is still available on, ClinicalTrials.gov does not remedy the Inventors' failure to disclose to the PTO that it previously had been publicly available.

Finally, the Court rejects Bausch's argument that Padagis fails to plead this omission was material. Of note, the Court disagrees with Padagis that this is an example of an "affirmative act[] of egregious misconduct" that would relive Padagis of demonstrating but-for materiality.

Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1292 (Fed. Cir. 2011). To the contrary, "[b]ecause neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct, claims of inequitable conduct that are based on such omissions require proof of but-for materiality." Id. at 1292-93. Notwithstanding, Padagis expressly alleges but-for materiality, see PAA at ¶¶ 69, 80, and these allegations find factual support in the PTO's Notices of Allowability. See, e.g., ECF No. 46-6 at ¶ 4 (allowing Invention in part because there were "no teachings or suggestions within the prior art that the combination of 0.01%wt. halobetasol-propionate with 0.045%wt. tazarotene . . . would result in providing synergistic efficacy and synergistic reduction of at least an adverse event"); e.g., Wyeth Holdings Corp. v. Sandoz, Inc., 2012 U.S. Dist. LEXIS 26912, at *31 (D. Del. Feb. 3, 2012) ("Sandoz did explicitly allege but-for materiality. After listing the various types of alleged misrepresentations made to the Examiner by Wyeth representatives, Sandoz asserted: 'Thus, the '828 patent would not have been issued but for [Wyeth's] deceptive and erroneous representations to the [PTO].' Moreover, Sandoz alleged that because the Examiner specifically acknowledged and cited many of the statements made by Wyeth's representatives when listing the Reasons for Allowance of the '828 patent, but-for materiality is a reasonable inference. Therefore, . . . the allegation of but-for materiality was squarely made.") (emphases and citations omitted).

The Court therefore will grant Padagis' request to amend its answer and counterclaims to include allegations of misconduct relating to NCT02045277.

V. Conclusion

An order consistent with this opinion follows.

Dated: October 6, 2021

/s/ Cathy L. Waldor
Cathy L. Waldor, U.S.M.J.